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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/087,871	06/02/1998	GERALD WAGNER	0708-4038	1082

7590   12/05/2001

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EXAMINER
GABEL, GAILENE

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 12/05/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
● **Office Action Summary**	09/087,871	WAGNER, GERALD
	Examiner	**Art Unit**	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed
  after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any
  earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _17 September 2001_ .

2a)☒ This action is **FINAL**.   2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is
   closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _1-21_ is/are pending in the application.

   4a) Of the above claim(s) _13-21_ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) _1-12_ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) _1-21_ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

   Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

   If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   a)☐ All b)☐ Some * c)☐ None of:

   1.☐ Certified copies of the priority documents have been received.

   2.☐ Certified copies of the priority documents have been received in Application No. _____ .

   3.☐ Copies of the certified copies of the priority documents have been received in this National Stage
      application from the International Bureau (PCT Rule 17.2(a)).

   * See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

   a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: _____ .

DETAILED ACTION

Amendment Entry

1.   Applicant's amendment and response filed 9/17/01 in Paper No. 14 is

acknowledged and has been entered. Claims 6-11 have been amended. Claims 1-21

are pending. Claims 1-12 are under examination.

Restriction Requirement

2.   Applicant's traversal of the restriction requirement in Paper No. 14 is

acknowledged. The traversal is on the grounds that the inventions are obvious over

each other within the meaning of 35 USC § 103.

Applicant's argument is not found persuasive because restriction requirements

are set forth for reasons of patentable distinction between each independent invention

so as to warrant separate classification and search. For example, it is technically

obvious to perform a method using a specified apparatus or system; however, each of

the method and apparatus/system is distinct and independent since the structural

requirements of each one as an invention are different. The record set forth in the

previous restriction requirement clearly indicated that the delineated inventions are in

fact patentably distinct each from the other or independent from the other. The

requirement is still deemed proper and is therefore made FINAL.

R j ctions Withdrawn

Claim Rejections - 35 USC § 112

3.   In light of Applicant's amendment and arguments, the rejection of claims 6-12

under 35 U.S.C. 112, second paragraph, is hereby, withdrawn.

4.   In light of Applicant's argument, the rejection of claims 1-12 under 35 U.S.C. 112,

first paragraph, is hereby, withdrawn.

Rejection Maintained

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set
> forth in section 102 of this title, if the differences between the subject matter sought to be patented and
> the prior art are such that the subject matter as a whole would have been obvious at the time the
> invention was made to a person having ordinary skill in the art to which said subject matter pertains.
> Patentability shall not be negatived by the manner in which the invention was made.

5.   Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Lillig et al. (US 4,965,049) in view of Groth et al. (US 5,690,103) and in further view of

Furlong et al. (Clinical Chemistry, 1990), for reason of record.

To reiterate, Lillig discloses a system combining analyzers, each adapted for

independent operation and each possessing different operational characteristics for

different applications wherein each modular analyzer is adapted to operate as a portion

of a system of modular analyzers (see column 2, lines and 8-26 and Figure 3). The

system includes a first analyzer and a second analyzer each including a sample

carousel, analyzing means, and automated probe means for transferring samples from the sampling carousels to the analyzing means. Electronic and electrical interfaces form public and/or private networks between analyzers so as to form the system and operational information and instructions are coded into the analyzers through a disk drive (see column 6, lines 51-65).

Groth teaches computer based neural networks design incorporated into analyzers where measured patient results (analyte concentrations, enzymatic activities, etc.) are compared and referenced with biochemical marker standards from preclassified example cases to provide an indication of a pathology. Groth discloses that the computer system is designed to perform specific computational tasks to support a decision tree that provides a feedback mechanism of what subsequent measurements are to be performed based on the most recent measure; the end product of which provides a diagnostic indication of a pathology (see column 5 and column 8).

Furlong teaches computerized neural network analysis specifically of cardiac data for use as clinical decision-making aid wherein computer hardware and software emulate biological nervous systems formed by interconnected artificial neurons (see page 135, column 1, first full paragraph). Such artificial intelligence programs use algorithmic process for decision making wherein clinicians knowledge has been distilled in a hierarchy of facts or rules wherein the matrix of synaptic weighting factors are calculated using back propagation, supervised learning algorithm (see page 134, column 2, last paragraph).

One of ordinary skill in the art at the time of the invention would have been

motivated to increase automated diagnostic versatility into the high-throughput capacity

of modular designed analyzer systems taught by Lillig by incorporating decision support

systems such as the computerized neural network as taught by Groth and Furlong

because in assessing proper emergency management of crisis patients, especially

those suspected of myocardial infarction, specific and accurate results obtained at a

limited amount of time coupled with anticipatory diagnostic procedure, are critical to the

treatment and survival of patients.

Response to Arguments

6.   Applicant's arguments filed 9/17/01 have been fully considered but they are not

persuasive.

A) Applicant argues that Lillig, Groth, and Furlong in combination fails to provide

Applicant's invention as a whole and there is no motivation or suggestion for modifying

the combination to arrive at the claimed invention. Specifically, Applicant contends that

neural network taught by both Groth and Furlong is a stark contrast to the reflex

algorithm claimed by Applicant because neural network classifies according to

predetermined set of biochemical markers and measurements which are fed into a

trained neural network, which is diametric to a reflex algorithm wherein determination of

a pathology is associated with different possible measurements.

In response, the determination of pathology associated with different possible

measurements in "reflex algorithm" is necessarily dependent upon predetermined set of

biochemical measurements programmed into software for use by the algorithm, in

addition to other different possible measurements, to effect a decision tree such as in a

neural network design which provides for feedback mechanism including a suggestion

to perform other activity or to activate another network structure which Groth refers to as

a "feedback connection from conclusive diagnostic unit" (see column 16, lines 42-67) so

that further testing, if desired, can be activated into preprogrammed analytical computer

software to further analyze a sample. Alternatively, Applicant, by way of admission at

page 2 of the specification, discloses that reflex algorithm has been employed in the

areas of clinical chemistry and laboratory medicine for the past decade. Therefore,

absent evidence to the contrary, the neural network system disclosed by both Groth and

Furlong can, otherwise, be designed and programmed to allow reflex algorithm

capability such as claimed in the instant invention.

7.   No claims are allowed.

8.   **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time

policy as set forth in 37 CFR 1.136(a).

     A shortened statutory period for reply to this final action is set to expire THREE

MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later

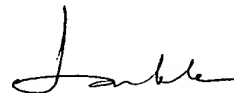than SIX MONTHS from the mailing date of this final action.

9.   Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Gail Gabel whose telephone number is (703) 305-0807.

The examiner can normally be reached on Monday to Thursday from 7:00 AM to 4:30

PM. The examiner can also be reached on alternate Fridays from 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Long Le can be reached on (703) 308-3399. The fax phone number for the

organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or

proceeding should be directed to the receptionist whose telephone number is (703) 308-

0196.

Gailene R. Gabel
Patent Examiner

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

12/03/0L